

3283 '98 APR -7 P12:51

**COMMENTS TO THE PROPOSED RULE:**

**Medical Devices; Refurbishers, Servicers, and "As Is" Remarketers of Medical  
Devices; Review and Revision of Compliance Policy Guides and Regulatory  
Requirements; Request for Comments and Information**

**DOCKET NO. 97N-0477**

**Presented to:**

**Dockets Management Branch (HFA-305)**

**Food and Drug Administration**

**by:**

**Paul J. James, Certified BMET**

**In-Hospital Medical Device Servicer**

**9108 - 34 1/2 Avenue North**

**New Hope, MN 55427**

*Original  
submission  
(slightly  
edited)*

*97N-0477*

*C 34*

### **Qualifications of Author**

I have been employed as a medical device servicing person (BMET) in a community hospital in Minneapolis, Minnesota for 18 years. I am a graduate of an accredited program in Biomedical Equipment Technology and certified by Hennepin Technical College in Eden Prairie, Minnesota. I am currently enrolled in a baccalaureate degree program at the University of Minnesota in **Health Technology Administration**. I have written hundreds of technical testing procedures, and have read and followed hundreds of manufacturers testing procedures. I am fully conversant with national and international standards in calibration and metrology, as well as Joint Commission on Accreditation of Hospital Organizations (JCAHO) standards.

### **Background Information**

Servicers of medical equipment routinely attempt to assure that devices meet manufacturer's published specifications during the post-marketing and use phase of their life-cycle. Unfortunately, certain specifications are not routinely published that would allow safe, effective, and efficient calibration assurance practices.

The two types of failure that occur with medical equipment are: **1) random**; and, **2) failure associated with parameters that fail to meet specifications due do a time-related function (sometimes known as “drift”, “loss of calibration”, or “uncertainty growth”)**.

Currently, hospitals, third-party service organizations, original equipment manufacturers, and accreditation agencies such JCAHO lack *consistent* policies regarding the frequency of routine testing of medical devices. **Organizations are left to establish their own policies, frequently without regard to accepted metrological practices. This results in heuristic systems that are inconsistent, often ineffective, and usually**

**inefficient.** Consistent methods need to be employed, and consistent specifications should be made available to all users and servicers of equipment.

**All calibration systems that assure the integrity of medical measurements should employ methods similar to those set forth in national and international standards such as ISO GUIDE 25, ANSI/NCCL Z540-1, NASA 5300.4, or U.S. DOD MIL-STD-45662A.** These standards require periodic intervals and methods be established to maintain acceptable accuracy and measurement reliability. Measurement reliability is defined as: *the probability that the equipment under test and the measurement standard will remain in-tolerance throughout the established interval.* This kind of system is designed to be both effective and efficient at addressing the needs of uncertainty growth.

### **Post Market Safety and Effectiveness**

The majority of Class 2 and Class 3 medical devices either make a measurement of a clinical parameter or deliver some kind of energy, drug, or bio-material to a patient. Thus the intrinsic safety and effectiveness of the device is compromised in the post-market use period if the device does not meet manufacturer's specifications or clinically acceptable specifications. If the calibration of these devices cannot be assured, then the clinical endpoints and patient benefits upon which the regulatory approval was granted cannot be assured.

The concept becomes clearer when one realizes that the effectiveness, or the use of the device under ordinary circumstances, is currently suspect due to poor or non-existent documentation, various levels of training by medical device users, servicers, and developers of the calibration and quality system, inconsistent practices in the field, and accreditation bodies that do not have expertise in metrology or calibration systems.

## Comments

**COMMENT #1:** In addition to current GMP requirements, manufacturers should be required to deliver servicing information with the delivery of the device. The information should recommend procedures and intervals based upon premarket and ongoing testing, as well as the following four statistics: **1) the parameter tolerance limits; 2) a specified period of time over which the value will be contained within the tolerance limits; 3) the *probability* that parameters will be contained within the tolerance limits for the specified period of time; and 4) mean time between random failure.**

Items 1 - 3 above address uncertainty growth and gives servicers a starting point for which to establish testing intervals for necessary parameter testing. Item 4 addresses random failure, which can be used to establish maximum testing interval length.

**COMMENT #2:** All refurbishers, rebuilders, reconditioners, servicers, and remarketers should be required to employ calibration systems that meet the above mentioned national or international standards, especially on the basis of ***measurement reliability***. Measurement reliability is the one standard that can provide consistency between all servicing organizations.

**COMMENT #3: :** All refurbishers, rebuilders, reconditioners, servicers, and remarketers could be required to report reliability to the original device manufacturer. Although the concept has some justification on the basis that the large amount of data collected could generate highly efficient interval analysis. However, the individual environment of use may provide enough difference in data to make the analysis invalid. Therefore, organizations should aggregate data according to the particular use

environment, and create their own measurement reliability data for the safest and most effective calibration intervals.

### **Benefits**

The benefit of regulating these parameters can be demonstrated by projecting the amount of resources currently utilized in unnecessary testing, which would occur when reliability is high and testing intervals are too frequent. Conversely, when reliability is low and testing intervals are too infrequent, **the integrity of the clinical measurement system, and thus the safety, effectiveness, and quality of patient care, is jeopardized.**

Further benefit is achieved by if servicers are required to report to manufacturers, data distinguished as random or time-related, thereby uniquely identifying the kind of manufacturing adjustments or periodic maintenance needs that might be necessary.

### **Specific Examples**

In my 18 years as a medical device servicer, I have **frequently** encountered either no service information, or a **lack** of service recommendations and statistics that enable developing a proper calibration system. This occurs on all types of devices, but unfortunately, even high-risk devices such as blood warmers, ventilators, and lithotriptors are subject to these abuses. This happens too frequently, and leaves the medical device servicer to “make-up” a test procedure.

Blood warmers are an excellent example, where the thermostats can drift out of calibration if not subject to a rigorous calibration program. I have recently been presented new state-of-the-art blood warmers with no servicing information! This has also happened recently with life-sustaining ventilators!

On the other hand, many devices maintain their accuracy and reliability over long periods of time. Most microprocessor-based instruments fall into this category. The maximum testing interval in this case can relate to mean time between random failure,

which is often very long. The amount of needless testing may be staggering. If all hospital based servicing departments could cut testing by 2000 hour per year, it would save approximately \$240,000,000 in needless testing alone!

Perhaps the most serious problem that post-market device servicers face is that hospital administrators and JCAHO compliance surveyors are not trained in the practice and philosophy of bench testing and measurement systems. Therefore, devices are routinely accepted for use with inadequate testing, documentation, and training, even though standards would seem to imply that these issues are considered.

The standards that I suggest be implemented and regulated would provide a consistent methodology for attacking these problems, as well as prevent ambiguities that still exist in this industry.

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**DOCKET NO. 97N-0477**

**Presented to:**

**Dockets Management Branch (HFA-305)  
Food and Drug Administration**

**SUBMISSION NUMBER 2**

**by:**

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9108 – 34 ½ Avenue North  
New Hope, MN 55427**

7 2 7 3 98 APR -7 AM 10:06

## **Background**

I have enclosed a paper prepared by myself and submitted to Dockets Management Branch several months ago to use as a reference with this submission. An excerpt from my first paper is provided again: “COMMENT: All refurbishers, rebuilders, reconditioners, servicers, and remarketers should be required to employ calibration systems that meet the above mentioned national or international standards (see first submission), especially on the basis of *measurement reliability*. Measurement reliability is the one standard that can provide consistency between all servicing organizations.”

Enclosed is correspondence printed from a listserve between two individuals currently debating the nature of appropriate medical device servicing practice. **It is very clear that practice is not consistent.**

It is not hard to speculate that because of hospital administrators’ lack of metrological knowledge and with the increased competition between third party servicers, manufacturers, and in-house technical staff, medical device assurance practices are widely inconsistent and perhaps unsafe. Pressure to reduce costs may force reduction of servicing activity. **There needs to be a reliable standard with which the industry can refer to in comparing cost, risk, and quality.** Measurement reliability accomplishes this because quantifiable probabilities can be established for known maintenance intervals, time and costs necessary to perform calibration procedures, and the acceptance of risk/cost ratios.

**Comment #1:**

21 CFR 809.10 concerning safety and effectiveness considerations, specifically refers to “device reliability.” My recommendation is that during post-marketing and use phases, reliability of a device should be described as: “*the probability that the equipment under test and the measurement standard will remain in-tolerance throughout the established interval.*” This is termed **measurement reliability**.

**Comment #2:**

HHS Publication FDA 96-4159, appendix e, 3.4 RELIABILITY ASSESSMENT outlines methods for reliability assessment. These methods are similar in nature and scope to my recommendations, and should be reviewed and employed for consistent regulatory effort.

**Comment #3:**

HHS Publication FDA 96-4159, appendix e, 3.4 LABELING outlines labeling review methods. Notice the requirement for recommended test and calibration protocols. The following elements should appear in any labeling requirements in order to provide proper protocols and design of valid systems based upon measurement reliability: **1) the parameter tolerance limits; 2) a specified period of time over which the value will be contained within the tolerance limits; 3) the *probability* that parameters will be contained within the tolerance limits for the specified period of time; and 4) mean time between random failure.**

### **EXAMPLES:**

The safety and efficacy of a drug, medical device, or test presumes adherence to engineering endpoints. For example, the efficacy of a drug relies upon administration either directly by a clinician via a syringe in a known dose, or by an infusion device in a known quantity at a known rate. Bench testing of calibrated engineering endpoints in manufacturing of either the syringe or the infusion device is therefore critical to safety and efficacy and is required in FDA Quality Systems and premarket approval processes.

In the case of the syringe, unless manufacturing quality control degenerates, delivery of the prescribed dose needs no further calibration assurance. The syringe is used once, and the calibration is explicit. In clinical practice however, the infusion device contains multiple parts with multiple interactions that could cause drug delivery specifications to perform outside of calibrated limits, thus engineering endpoints are not attained, and effective therapy is jeopardized.

In practice, there are hundreds of devices that may exhibit growth of uncertainty related to the accuracy of their calibration. **These devices make measurements used for clinical decisions, or deliver some form of energy or medication directly to the human patient.**

The most recent examples of problems related to inconsistent servicing of medical devices at our hospital include a blood warmer, a ventilator, a humidification system for ventilator patient circuits, and an intra-cardiac ablation system, all shipped and delivered without servicing information. In our case, we required that manufacturers provide that information. I wonder if all hospitals make that requirement.

Our hospital was recently surveyed by the Joint Commission on Accreditation of Hospital Organizations. No inspection was made of proper servicing methods during the survey. In addition, no inspections of our device acceptance policies were made, only inquiries about policy existence. It is argued that there is enough voluntary regulation in place. I differ from that perspective. I believe that no one is rigorously inspecting or requiring appropriate methods. Due to staff cutbacks and poor management, our hospital went years behind with some critical device preventive maintenance inspections. Over 1000 inspections were delayed greater than 30 days. In one case an incident was filed on an oxygen blender when it failed to deliver the proper O2 concentration to a neo-natal newborn. The device was long overdue for maintenance.

Author: Bob Johnson at Maintenance  
Date: 3/23/98 8:52 AM  
Priority: Normal  
TO: Carol Andersohn  
TO: Paul James  
Subject: Re: About regular inspection of Merlins and other "stationar

THIS WAS SENT  
ETO ME FROM  
MY SUPERVISOR.

COPY OF  
CORRESPONDENCE  
FROM AN OPEN  
LISTSERVE

----- Forwarded w/Changes -----  
Author: Biomedical Engineering Discussion List <BIOMEDTALK-L@LISTSERV.AOL.COM>  
at The-World 3/23/98 7:53 AM  
TO: BIOMEDTALK-L@LISTSERV.AOL.COM at The-World  
Subject: Re: About regular inspection of Merlins and other "stationar  
----- Message Contents -----

FYI

THIS WAS THE  
REPLY FROM  
THE ORIGINAL  
COMMENT  
↓

----- Forward Header -----  
Subject: Re: About regular inspection of Merlins and other "stationar  
Author: Biomedical Engineering Discussion List  
<BIOMEDTALK-L@LISTSERV.AOL.COM> at The-World  
Date: 3/23/98 7:53 AM

I agree with you, but hear the other side. Our job is to find problems and correct them. It is also to increase productivity and save our hospitals money. As your situation is considered, if you have a problem with cords being stressed on the mount, make the cord longer. As far as the simulator is concerned, a simulator is not necessary to check accuracy of the monitor. Insert all modules into the Merlin and run "TEST SIGNALS". By doing this, a cal signal is put on the very front end of the module. H/P has specs in the service manual on what the values displayed should be. The nurse will tell you if a signal is noisy so that leadwires can be replaced. We use to spend an hour for every monitor twice a year. We have roughly 40 monitors. This translates to 80 hours a year doing PM's on something we cannot prevent from failing. Our PM now consists of a visual inspection of all cables and we run "TEST SIGNALS" on each monitor once a year. This takes roughly 30 minutes each monitor assuming we find a bad overlay. We saved 60 hours of technician time by doing this. As far as outsourcing goes, what do you think an outsource company will do? They will do exactly what I am saying. This is why we MUST decrease the amount of time spent doing insignificant PM checks. I'm not saying to overlook anything, just use your judgment as a BMET to make logical decisions on the support of equipment.

Russell L. Cain  
Biomedical Supervisor  
St. Anthony Medical Center  
Crown Point, IN.

THIS WAS THE  
ORIGINAL  
COMMENT

↓

JoltmanPA wrote:

> Just a passing note.....  
>  
> I had mentioned this before and I feel the need to mention it again.... while  
> HP Merlin monitors might be "mounted" they are FAR from "STATIONARY"!!!! They  
> rotate!!! I have seen two monitors during my last round of inspections in the  
> ICU where the ground wire had been yanked from the plug due to the monitor

> power cord having been wrapped around the mounting arm and pulled tight when  
> the monitor was rotated. While the patient connections are isolated, I still  
> felt better about doing a complete safety test.  
>  
> Also.... how about hooking up the ECG cables to your simulator and making sure  
> the numbers being displayed for heart rate and respirations are accurate??  
> While I have never seen an HP module that didn't accurately reflect the  
> simulator output, the HPs are in the critical care areas, and as the Biomed  
> Golden Rule... if your wife, daughter, son, etc were hooked up to that monitor  
> in the CCU wouldnt you want to know that it was tested for accuracy???  
>  
> Jay Kupiszewski  
> JoltmanPA@aol.com  
>  
> p.s..... Don't be so quick to try and find LESS work for yourselves.... there  
> is always a third party outfit that would LOVE to do your work for you!!!!  
>  
> Mikes reminder of the day, - If possible, quote some of the message you are  
> replying to. Try to put your additional comments at the beginning of the  
> message.

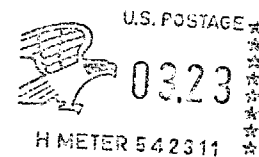
Mikes reminder of the day, - Want the digest version with only one mail each  
day? Send the command SET BIOMEDTALK-L DIGEST to [LISTSERV@LISTSERV.AOL.COM](mailto:LISTSERV@LISTSERV.AOL.COM)

~~Mr. James~~  
1108-34 1/2 Ave N  
New Hope, MN 55427

CERTIFIED

P 248 978 346

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